

Line 13 makes reference to Fig. 4, which clearly shows the shutter system 22, the radiation rays 28 passing through the patient 17, and then detected by detectors 53 distributed on an arc with the source of the radiation defining the center of the arc. Lines 15-18 specifically state that the radiation goes through the patient and are then detected by detectors. Lines 22-25 describe how the detection of the radiation after going through the patient is compared to the amount of radiation expected, based upon the intended amount of radiation and the expected attenuation of that amount of radiation by the patient. Lines 37-on describe how the post detected signals at 53 are used to verify if the shutter system is functioning properly.

In contrast, the process described in our invention describes a method that may be employed to verify if patients are receiving or will receive the correct amount of radiation when those patients are treated on gantry mounted radiation machines. This is accomplished by measuring the radiation field for each intended treatment beam. It makes no difference whether in fact the patient is in the process of being treated or if a dry run is being made without the patient. This measurement must be performed at some known distance from the source of x-rays, in a plane perpendicular to the central ray of the radiation beam. Each measured radiation beam is used as input to a dose calculation algorithm to reconstruct the dose that patient will receive. To accomplish this, each measured radiation beam must be normalized to the machine's monitor unit system for a known calibration condition, i.e., the field size at which the machine's calibration is specified. The dose algorithm must likewise be normalized to the same calibration condition, the normalization process using as input to the dose algorithm a known or measured fluence field for the calibration condition likewise normalized to the machine's monitor unit system. Under these circumstances, the measured field fluence for the treatment beams can be used to compute the absolute dose to the patient.

The Olivera describes a system to actively control their machine, and involves processes and hardware arrangements significantly different than the process we describe to reconstruct the patient dose for gantry mounted machines. Olivera col. 7, lines 66 to col. 8, line 33, does not describe calculating the dose to the patient with a dose algorithm. Rather it describes a process to solve for the $d_{i,j}$ parameters that represent the signal received by detector i for one unit of energy fluence exiting the shutter system 22 at leaf j (col. 7 lines 60-63). The purpose of obtaining these values is stated in col. 8, lines 20-30, so that the operation of the shutter system 22 may be verified by the signals $S_i(t)$ from the post-patient radiation detector 53. We note here that the machine may be operating perfectly but the patient dose might still be wrong if some person made some mistake in the planning stage. Our process, for gantry mounted machines, reconstructs the patient dose. If the dose is not as intended or expected, the cause could be any number of factors, machine error or human error, either in the planning stage or in the delivery stage.

In Olivera col 9, lines 44-66, the fluence is derived from the dose measured at the exit side of the patient by measurement of the exit dose by the post-patient detectors 53. In our process, the fluence is directly measured. It would be difficult if not impossible to apply the process described by Olivera to gantry mounted machines. On gantry mounted

machines, because the patient is not translated through a narrow beam, narrow in the longitudinal direction of the patient, the patient support system by necessity will also be intersecting the beam, introducing further modulation of the beam. Because the beam is not normally collimated into pixels or controlled by shutters as in the geometry of the tomotherapy machine, the process of deriving the effects of pixels as depicted in Olivera Fig. 6 and 7 will be difficult to perform. Further, the gantry mounted machine would have to be modified to include a post irradiator detector that would be suitable for measuring the exit dose and would avoid collisions with the patient and patient support system. A system has been described by Hughes, patent number 5,754,622, and is considered by the patent office to be a separate and distinct process. Our process is separate and distinct in that it uses a fluence measured before the patient rather than after transversing the patient. An advantage of measuring the input fluence is the elimination of the uncertainty introduced by deriving the input fluence from an exit dose measurement. The uncertainty can easily be so large as to render the dose computed to the patient to be of little use in verifying the correctness of the dose, as the range of the dose values due to the accumulation of the uncertainties introduced in computing those numbers may be too large. The distinguishing step in our process is measuring directly the input fluence and using that measured fluence to compute the patient dose. The resulting process is less complicated, more accurate, and more directly applicable to the use of gantry mounted radiation machines.

In (4) of the office action of 5/7/2003, it is stated the Olivera discloses that the verification process may be implemented without the patient being present in col. 8, lines 41-46 and col. 9, lines 23-43. However, in col. 8 lines 41-46, the patient is replaced with a phantom that is to approximate the patient. This phantom is present to derive the above mentioned elements d_{ij} and has nothing to do directly with verifying the patient dose. In col. 9, lines 23-43, again a phantom is used instead of a patient to find the values of the d_{ij} parameters. The d_{ij} parameters are needed and used to estimate the amount of radiation leaving a shutter based on a measurement after the radiation ray has transversed the patient. This whole section refers to a feedback mechanism for verifying the operation of the tomotherapy machine's shutter mechanism (col. 9, line 45). In col. 9 line 46-51, if the patient is in fact used to measure the parameters d_{ij} , then the dose delivered to the patient during that measurement process should be subtracted from the intended treatment so that the end result is not changed. The process being described uses various means for obtaining the parameters d_{ij} . In Olivera the dose to the patient is computed by a process that uses an exit measurement, the exit measurement used to estimate the actual shutter opening by use of the d_{ij} parameters, and the shutter opening used to estimate the input fluence from which the patient dose is computed. The patient dose is thus optimally estimated from the exit measurements. The verification process in col. 8 20-39 and 46-48 is that of verifying the shutter opening during patient treatment.

In (6), the specification includes a description of the normalization process necessary to apply a measured fluence to a dose algorithm.

In (7), the inventor is open to any rewording of the claims that the examiner may believe is appropriate.

Conclusion

For all of the above reasons, applicant submits that the claim is now in proper form, and that the claim defines patentably over the prior art. Therefore he submits that this application is now in condition for allowance, which action is respectfully solicited.

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Date: *July 8, 2003*

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My Commission Expires 10/28/2006

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